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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,625	06/22/2001	Yoshihiko Makino	JG-YY-5090 / 500569.20069	7410

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REED SMITH LLP  
375 Park Avenue  
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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/887,625**

Applicant(s)  
**Makino**

Examiner  
**Arun Chakrabarti**

Art Unit  
**1634**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on May 27, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☒ Other: **Detailed Action**

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2003 has been entered.

### ***Specification***

2. Claim 1 has been amended. Claim 1 is objected to because of the following informalities: There is a spelling mistake on line 3 of the claim which recites "oe sample". It should be rewritten as "one sample". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 1 is rejected over the recitation of the phrase, "consists essentially of". In absence of a definition of the term either in the specification or in the claim, it is not clear what is essential to disclose the novelty and basic feature of the claimed invention. The metes and bounds of the claims are vague and indefinite.

The term "consists essentially of" in claim 1 is a relative term which renders the claim indefinite. The term "consists essentially of" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Mathies et al. (U.S. Patent 6,361,671 B1) (March 26, 2002).

This rejection is based on the fact that the term "consists essentially of" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Therefore, the claim language allows any other step(s) or materials(s) to be added in any order with the steps of claimed invention.

Mathies et al teach a method of detecting nucleic acid fragments in plural samples (Abstract) which comprises the steps of:

a) attaching an electroconductive label to nucleic acid fragments in one sample and attaching another electroconductive label to nucleic acid fragments in another sample, the former electroconductive label and the latter electroconductive label having oxidation-reduction potentials differing from each other (Claims 8, and 26-42 and Column 10, lines 14-26);

b) preparing a mixture of the samples containing nucleic acid fragments to which electroconductive labels are attached (Claims 8, and 26-42 and );

c) bringing the mixture into contact with an electroconductive microarray having plural electrodes onto which probe molecules complementary to the nucleic acid fragments are fixed, so that hybridization between the nucleic acid fragments having electroconductive labels and the probe molecules on the electroconductive microarray can proceed to form hybrid structures on the electrodes (Column 8, line 55 to Column 9, line 6 and Column 10, lines 46-55 and Figure 1);

d) applying to the electrode an electric potential corresponding to the oxidation-reduction potential of the former electroconductive label and detecting on the electrode an electric current flowing along the hybrid-structure (Figures 4-5 and 8-9 and Claim 41);

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e) applying to the electrode an electric potential corresponding to the oxidation-reduction potential of the latter electroconductive label and detecting on the electrode an electric current flowing along the hybrid-structure (Figures 4-5 and 8-9 )  
and

f) comparing the electric current detected in the former detecting procedure and the electric current detected in the latter detecting procedure to obtain a ratio of the content of the nucleic acid fragments in each sample (Figures 4-5 and 8-9 ).

Mathies et al teach a method, wherein the probe molecules are nucleic acid fragments (Claims 26-42 and column 10, line 14 to column 11, line 45).

Mathies et al teach a method, wherein the probe molecules are peptide nucleic acid fragments (Column 11, lines 22-26 and Column 12, lines 29-36).

Mathies et al teach a method, wherein the oxidation-reduction potential of the latter electroconductive label differs from the oxidation-reduction potential of the former electroconductive label by at least 50 mV (Figures 4A and 4B and Column 7, lines 60-63).

Mathies et al teach a method, wherein the oxidation-reduction potential of the former electroconductive label and the oxidation-reduction potential of the latter electroconductive label both are in the range of 0 to 800 mV (Figures 4A and 4B and Column 7, lines 60-63).

Mathies et al teach a method, wherein the detection of electric current on the electrodes are conducted by differential pulse voltamography (Figures 4A and 4B and Column 8, lines 30-40).

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Mathies et al inherently teach a method, wherein one sample is obtained from normal cells and another sample is obtained from abnormal cells corresponding to the normal cells (Claims 41 and 42 and Column 3, lines 38-53 ).

Mathies et al inherently teach a method, wherein one sample is obtained from wild strain and another sample is mutant thereof (Claims 41 and 42 and Column 3, lines 38-53). This inference is deduced from the fact that polymorphisms and mutations are detected compared to normal cells or wild strain.

***Response to Amendment***

8. In response to amendment, a new 112 (second paragraph) rejection has been included and the previous 102(e) rejection has been maintained properly.

***Response to Arguments***

9. Applicant's arguments filed on May 27, 2003 have been fully considered but they are not persuasive. Applicant argues that 102(e) rejection should be withdrawn because cited reference of Mathies et al teaches an extra step of chromatography or electrophoresis of nucleic acid before its detection, which is not required by virtue of the amendment of the claim language. This argument is not persuasive. The 102(e) rejection is hereby properly maintained, which is based on the fact that the term "consists essentially of" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

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not be reasonably apprised of the scope of the invention. Therefore, in absence of the disclosure of the novelty and the basic characteristic features of the claimed invention, the claim language allows any other step(s) or materials(s) to be added in any order with the steps of claimed invention.

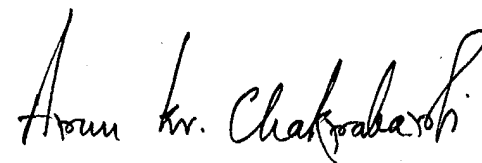
***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

June 25, 2003

  
**ARUN K. CHAKRABARTI**  
**PATENT EXAMINER**